Claim 20 (am [illegible]A method of treating disorders ar [illegible]i es associated with NPY receptor subtype Y5 comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of claim 1 selected from the group consisting of eating disorders, obesity, anorexia nervosa, bulimia nervosa, diabetes, dyspilipidimia, hypertension, memory loss, epileptic seizures, migraine, sleep disorders, pain, sexual/reproductive disorders, depression and anxiety.

a1

Claim 22 line 1 delete "Claim 21" and substitute therefor ---Claim 20------.

REMARKS

The Office Action dated September 22, 2000 has been carefully reviewed. Claims 1-22 are presented for examination. Claims 1-14 and 19-22 are rejected. Claims 15-18 are withdrawn from consideration as being drawn to a non-elected invention.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 and 19-22, drawn to a compound of formula A, a pharmaceutical composition and a method of use, classified in class 546, subclass 190, 200.

II. Claims 15-18, drawn to a compound, classified in class 548, subclass 427.

The Examiner has concluded that Groups I-VI (it is believed that Groups I-II were intended) are directed to structurally dissimilar compounds such that the variable positions of the substituent on hetero ring created by varying the definitions of the formula do not belong to a recognized class of chemical compounds in the art and references anticipating one invention would not render obvious the others. With this conclusion applicants take exception.

All of the claimed compounds are substituted tricyclic ring compounds having various substituents on one or more of the rings. Even though, as indicated by the Examiner, N-substituted rings are different from carbon substituted rings, the basic nucleus for all of the

compounds remains . e. In order to be included in the ıe lication the compounds need not be functional equivalents of each other. The search will essentially involve a search of the various substituents attached to the tricyclic ring nucleus. It is submitted that the search will not be unduly burdensome and that, therefore, all of the compounds should be examined in the same application. Reconsideration of the restriction requirement under 35 U.S.C. 121 is courteously requested.

During a telephone conversation with Mr. John Harbour on September 8, 2000 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-14 and 19-22. Applicants hereby affirm this election.

The Examiner has acknowledged applicants' claim for domestic priority under 35 U.S.C. 119(e). The Examiner has concluded that the provisional application, 60/132,660, upon which priority is claimed, fails to provide adequate support under 35 U.S.C. 112 for claims 1-22 of this application. The Examiner has further concluded that the provisional application does not disclose that the sulfonamido substituents are at the 2-position of the benzoindole ring but rather are N-substituted to the benzoindole ring. The Examiner's attention is directed to page 30, lines 10-15 of the provisional application. In scheme 3 on the cited page compounds wherein the sulfonamido group is at the 2-position of the benzoindole ring are described and prepared. Thus, compounds wherein the sulfonamido group is positioned at the 2-position and wherein the sulfonamido group is N-substituted are described and prepared in the provisional application. In addition, compounds wherein the sulfonamido group is attached at the 2-position are claimed in claims 15 and 17 of the provisional application. The provisional application, therefore, is a proper basis for applicants' claim for domestic priority under 35 U.S.C. 119(e).

Claims 1, 2 and 19-22 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which is pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner concluded that no sufficient testing was provided for any of the compounds listed in the specification. Applicants submit that test data for a representative number of the instant compounds falling within the generic claims are included in the specification on pages 52 and 53. It is submitted that test data are not required for each and every compound encompassed by the generic claim. The Examiner states that "Markush claims must be provided with support in the disclosure when the 'working examples' fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms". Although the definitions of the various R variables on the tricyclic ring system embrace many structurally divergent groups it is submitted that methods for preparing compounds having the various Markush members are described in various reaction schemes in the specification on pages 28-36. In addition, on page 37 of the specification methods are described for preparing those compounds having varied Markush members for Z, R_2 R_3, R_4, L and B. The Markush claims, therefore, are adequately supported in the specification. Since all of the compounds have the same tricyclic nucleus, it is submitted that the claimed compounds have the claimed utility and that the data submitted with the application as filed are sufficient to support the generic claim.

The Examiner has indicated that this area of activity can be expected to be highly structure specific and unpredictable, however, the Examiner has not set forth a basis for this conclusion. As indicated above, all of the claimed compounds have a tricyclic ring nucleus. The various substituents questioned by the Examiner are substituents on the tricyclic ring system. Applicants have submitted a representative number of compounds having the claimed activity. There is no reason to suspect, therefore, that any of the claimed compounds having the same tricyclic ring nucleus would not have the claimed activity.

Claims 20-22 are drawn to a method of treating disorders associated with NPY receptor subtype Y5. The Examiner has requested evidence of art recognized efficacy for the intended uses. The utility for compounds which act as Y5 antagonists is an art-recognized utility as evidenced by a number of patents issued by the U.S. Patent and Trademark Office. For example, U.S. Patent No. 6,048,900 issued on April 11, 2000 and discloses amide

derivatives which ar . ive neuropeptide Y receptor an or . In column 1 of the patent it is disclosed that antagonists of the Y5 receptor are used in treating, among other things, obesity, diabetes, dyspilipidimia, sleep apnea, memory disorders, epilepsy and depression. Although claims 7, 8 and 9 are limited to obesity and eating disorders, claim 1 is generic and claims a method for treating mammalian disorders mediated by the NPY Y5 receptor with no limitation to a specific disorder. The same is true for U.S. Patent No. 5,939,462 which issued on August 17, 1999. The generic claim (claim 1) is not limited to a specific disorder mediated by the NPY Y5 receptor. Thus, the claimed utility covers a broad scope even though claims 9, 10 and 11 of the '462 patent are limited to bulimia and obesity. U.S. Patent No. 6,140,354 issued on October 31, 2000. Claims 20-22 of the '354 patent are method of treatment claims. Claim 20 is the broadest claim and claims a method of treating disorders and diseases associated with neuropeptide receptor subtype 5. Claim 22 is a dependent claim and claims a method of treating disorders or disease states caused by eating disorders, obesity, bulimia nervosa, diabetes, hypertension, memory loss, epileptic seizures, etc. It is submitted that, in view of the fact that Applicants' claimed utilities are art recognized as evidenced by the disclosure and claims of the above patent, no additional evidence relating thereto is required.

Claims 2 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that claim 2 recites the limitation "alkyl", "alkoxy", "alkylene", "aryl" etc. The Examiner further concludes that there is insufficient antecedent basis for this limitation in the claim since in claim 1 the corresponding variables are defined as "C_{1-8}alkyl", "C_{1-8}alkoxy" "naphthyl" etc. It is submitted that claim 2 is dependent on claim 1. Therefore, any reference to alkyl, alkoxy, alkylene etc. in claim 2 must be interpreted in the light of claim 1. Since alkyl in claim 1 is defined as C_{1-8}alkyl, it stands to reason that alkyl in claim 2 can only be C_{1-8}alkyl.

Claim 19 recites the limitation "alkyl," "alkoxy," "alkylene," "aryl" etc. The Examiner has concluded that there is insufficient antecedent basis for this limitation in the claim. This is the same argument made with regard to claim 2 above. Applicants submit that claim 19 must be interpreted in view of claim 1 wherein alkyl, alkoxy, alkylene etc. are clearly defined.

The Examiner has concluded that claim 19 appears to be a substantial duplicate of claim 2. By the present amendment the dependency of claim 19 is being amended to read on claim 15 instead of Claim 1. It is believed that this amendment removes any duplication between claims 2 and 19.

The Examiner has concluded that claims 20 and 21 are of indeterminate scope for the following reasons: 1) no one particular disorder is recited; 2) the claim language may read on diseases not fully understood to be affected by NPY Y5 receptor antagonists; and 3) how does one determine who "is in need of such treatment" and who is not.

By the present amendment claim 21 is being deleted. Claim 22 is being amended to be dependent upon clam 20 instead of 21. The diseases recited in the claims are known to be affected by NPY Y5 receptor antagonists as indicated by certain issued patents. The Examiner has not given a reason for applicants to conclude otherwise. Obviously, one would only administer the compound to someone who suffered from one or more of the disorders treated by the receptor. If the party did not have a disorder to be treated there would be no reason to give that party the compound. It is submitted that the language employed in the claims is commonly used in applications drawn to pharmaceutical compositions and appears in one or more issued patents. It is also submitted that the language in question has been deemed to be acceptable by the Patent and Trademark Office and is, therefore, acceptable.

Claims 1-14 and 19-22 are rejected under 35 U.S.C. 102(a) as being anticipated by McNally *et al.* cited by the Examiner. The Examiner has concluded that McNally teaches the

compounds, compos[redacted]nd methods of use of the instant e[redacted]n. The publication date of the McNally reference is March 7, 2000. Applicants' effective filing date is May 5, 1999. Since applicants' effective filing date is prior to the publication date of the reference, it is submitted that applicants' invention is not anticipated by McNally *et al.*

In view of the above discussion and the amendments herein being made to the claims, it is believed that all of the outstanding objections and rejections have been removed. A favorable disposition of the application is requested.

Respectfully submitted

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